REMARKS

In the Office Action that issued on June 9, 2009, each of claims 1-52 were rejected. By way of this Amendment and Response to the Office Action, claims 1-52 remain as previously presented, and new claims 53-59 are added. Applicants note that claims 1, 18-20, 31 and 42 remain the only independent claims in the Application. Applicants respectfully submit that the newly added claims are fully supported by the Application as originally filed and that the amendments to the claims add no new matter to the Application.

Rejection under 35 U.S.C. § 103

Claims 1-13, 15, 16, 18-37, 39-48, and 50-52 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,552,148 to Hardy, Jr. et al. (hereafter "Hardy") in view of U.S. Patent No. 6,503,259 to Huxel et al. (hereafter "Huxel"); and claims 14, 17, 38, and 49 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hardy in view of Huxel, and further in view of U.S. Patent No. 5,868,763 to Spence et al. (hereafter "Spence"). The Applicants respectfully traverse these rejections.

It is well settled that the Patent Office bears the burden of establishing a *prima facie* case of obviousness. To meet this burden, the Patent Office must set forth an explicit analysis supporting an obviousness rejection. M.P.E.P. § 2142 (8th ed., rev. 6).

In particular, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting in re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). If the evidence presented in the analysis does not meet the preponderance of evidence standard (i.e., the evidence fails to show that it is more likely than not that an obviousness rejection is proper), then the rejection fails to set forth a *prima facie* case of obviousness. *See id.* Moreover, if "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 (VI).

The Applicant respectfully asserts that the rejections in the Office Action fail to set forth a *prima facie* case of obviousness for at least the reasons that (1) the asserted rationale for combining the teachings of Hardy and Huxel fails to meet the preponderance of evidence standard with respect to the propriety of their combination and (2) the proposed combination would change the principle of operation of each of Hardy and Huxel. Brief descriptions of each of the disclosures of Hardy and Huxel are set forth hereafter, followed by an analysis of each of the enumerated reasons that the obviousness rejection set forth in the Office Action fails to set forth a *prima facie* case of obviousness.

Hardy

Hardy discloses an anastomotic device 28 that consists of two separate unitary pieces, each of which defines a ring member. As shown in FIGS. 18-20 (reproduced below), each piece is joined to a separate free end 20, 22 of a tubular member 24, 26. Column 4, lines 52-63. Specifically, each of the free ends 20, 22 is stitched with a purse-string suture 52, and use of this suture permits engaging the very edge of the free end of the vessel wall so that the suturing material can be pulled and the vessel end contracted much in the way the top of a purse or string-closed bag is manipulated. *Id.*

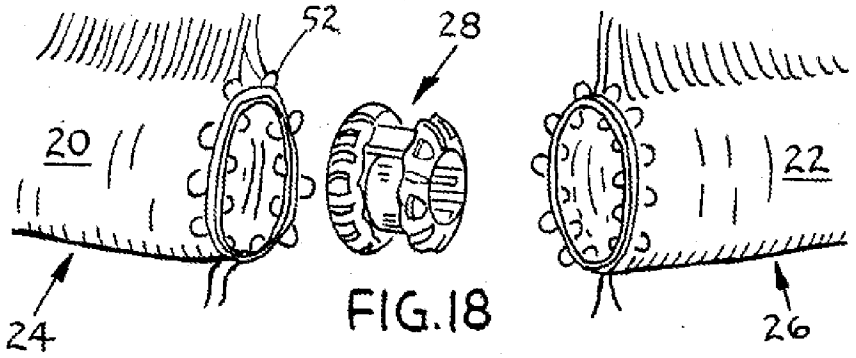

FIG. 18 of Hardy

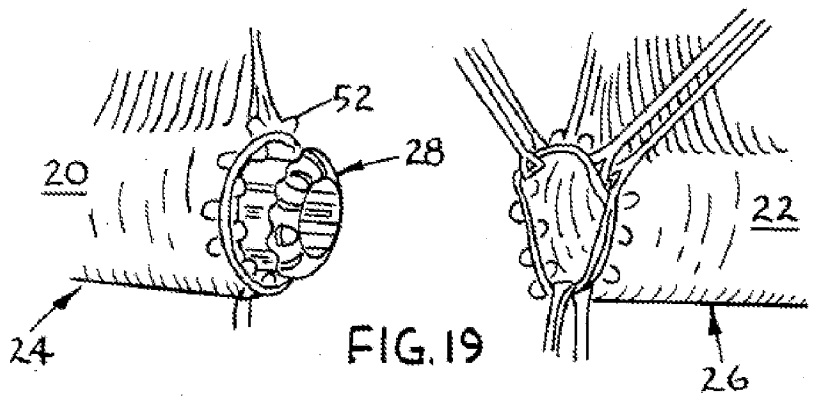

FIG. 19 of Hardy

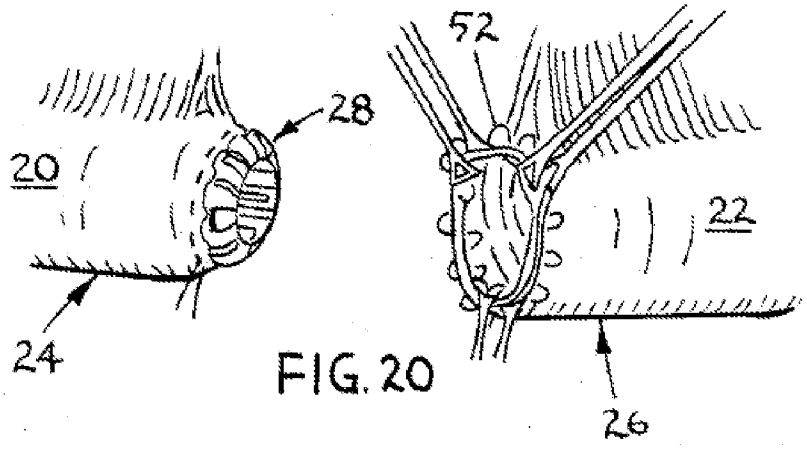

FIG. 20 of Hardy

The arrangement in which the tubular wall ends 20 and 22 are pulled over each ring member and are turned inwardly over the ring members is also shown in FIG. 8 (reproduced below). *Id.* As shown in this drawing, each of the two separate unitary pieces includes pawls 42 that are configured to interact with slots on prongs of the other separate unitary piece. As can be seen by comparing FIGS. 8 and 9 (FIG. 9 is also reproduced below), each pawl 42 includes a "sloping forward edge," which allows the

prong to move in one axial direction toward a locked position, and a "vertical engaging edge," which engages with a slot of a prong to prevent the prong from moving out of the locked position. Column 4, lines 1-8. To create an anastomosis, the two separate unitary pieces are urged together until the pawls 42 are engaged within the slots. Column 4, lines 60-68. This results in the ends of the tubular members 24, 26 being contiguously positioned in a manner that will enable them to grow together permanently. Column 5, lines 1-4. This contiguous positioning occurs without penetrating the tubular member free ends. Column 6, lines 40-43. As summarized in the Abstract, "securement structures are associated with the annular connecting structures to enable the securement of the ring members in a fixed relationship at a predetermined distance from each other."

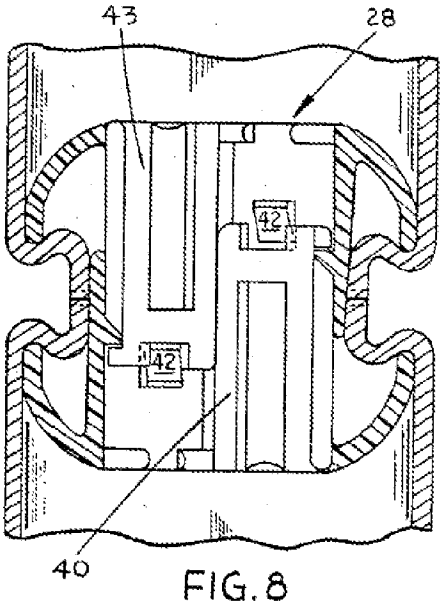

FIG. 8 of Hardy

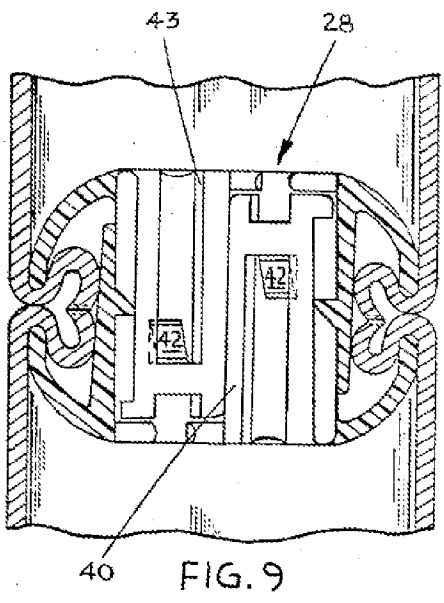

FIG. 9 of Hardy

Hardy states that "it is necessary [that the pieces] of device 28 be made from a material that will permit disintegration of the device in a relatively short period of time once healing of the vessel ends commences." Column 4, lines 42-46. This is because "a permanent connector will tend to prevent the changes in diameter which are necessary for the proper functioning of the intestine." Column 1, lines 56-64. Accordingly, Hardy clearly does not disclose that a diameter of the anastomotic device 28 can change after the device 28 is implanted. Rather, the device 28 maintains a fixed diameter and is configured to disintegrate in order to permit the proper functioning of the intestine (e.g., peristalsis of the intestine). Although, as noted in the Office Action, Hardy states that a "variety of diameters and spacings for the ring members and diameters for the annular coupling tube are desirable to provide needed versatility of use within the needed sizes for animals and humans" (column 5, lines 39-42), this passage only contemplates that different anastomosis devices 28 each may have a different *fixed* diameter, and further indicates that different devices must be provided to achieve different spcaings. It clearly does not contemplate that a variety of diameters or spacings are possible for a single anastomosis device 28.

Huxel

Huxel explicitly teaches away from devices such as those disclosed in Hardy, as this reference "criticizes, discredits, [and] otherwise discourages" the use of such devices. M.P.E.P. § 2143.01. For example, within its "Background of the Invention"

section, Huxel states that "suturing is not preferred in certain circumstances due to the inaccessibility of one or both of the ends to be joined an/or the time and high degree of mechanical skill involved for performing the anastomosis." Column 1, lines 26-30. Recall that the devices of Hardy specifically require the creation of purse-string sutures for their proper operation.

Moreover, Huxel states that certain problems with prior art anastomotic devices have "been addressed by biodegradable anastomotic fastening systems which break down in the presence of bodily fluids at a predetermined rate. . . [and such] known ring-type fastener systems provide a rigid anastomosis, limiting the radial expansion of the anastomosis and interrupting peristalsis." Column 1, lines 42-45 and 64-67. Recall that this is the exact manner in which the devices of Hardy function.

Additionally, Huxel states that "[k]nown mechanized anastomosis fastening systems generally require tissue thickness to be measured to select an appropriate fastener and to avoid over compression or incomplete apposition. Accordingly, a variety of fastener sizes must be available to accommodate varying tissue thicknesses." Column 1, lines 59-64. Recall that the devices of Hardy couple with each other at predetermined distances, and thus multiple devices are required in order to "provide needed versatility of use within the needed sizes for animals and humans." Hardy, column 5, lines 39-42.

All of the foregoing features are characterized by Huxel as "limitations" of the prior art, and further states that these limitations "are addressed by the present invention." Column 5, lines 1-5. Thus, Huxel clearly teaches away from the use of anastomotic devices such as those disclosed in Hardy.

As discussed at length in the Amendment and Response dated October 29, 2007, the devices of Huxel operate in a much different manner than do those of Hardy. Note that Hardy is a continuation of the Hardy patent (U.S. Patent No. 4,467,804) that was discussed in that Amendment and Response, thus the discussion in the prior Amendment and Response is equally applicable here.

As shown, for example, in FIGS. 1 and 8 (reproduced below) and as described in columns 3 and 4, the device of Huxel comprises a plurality of components that are positioned in a circular arrangement and remain discrete before and after they are attached together. Each of the fasteners 11 comprises a tissue piercing element 12 and a receiver element 14. Each of the fasteners 11 is structurally independent, and the plurality of fasteners "approximate concentric segmented rings." Column 3, lines 36-47 and 59-60. Each interlocked pair 12, 14 is structurally independent from any other pair of interlocked pair of interlocked elements 12, 14, allowing the interlocked pairs of elements 12, 14 to move independently of the others, being constrained and held in relative proximity by their affixation to a common substrate, e.g., peripheral flanges of tissue on the conjoined severed ends of the intestine. This relative structural

independence gives rise to what can be described as "flexibility" of the fastener array 10. Column 3, line 66 and column 4, lines 1-7. Clearly, it is essential to the operation of the device of Huxel that the tissue piercing element 12 pierce through the ends of both tubes that are being anastomosed.

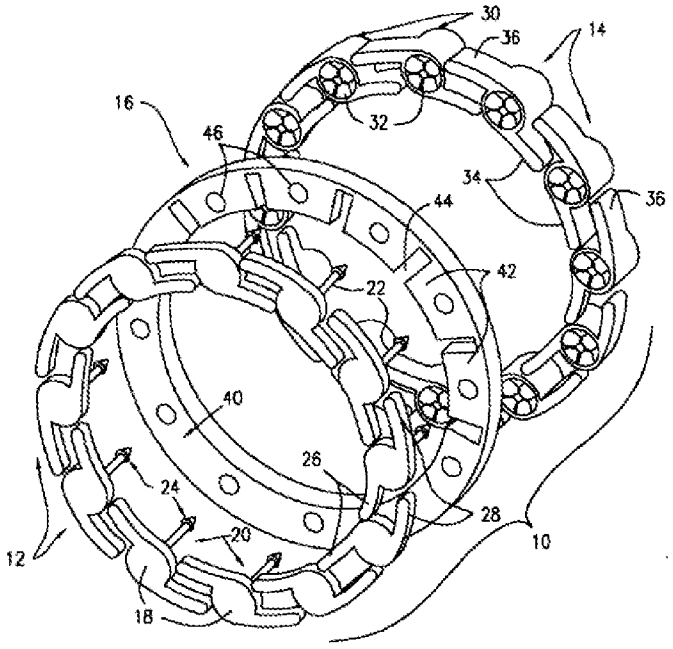

FIG. 1 of Huxel

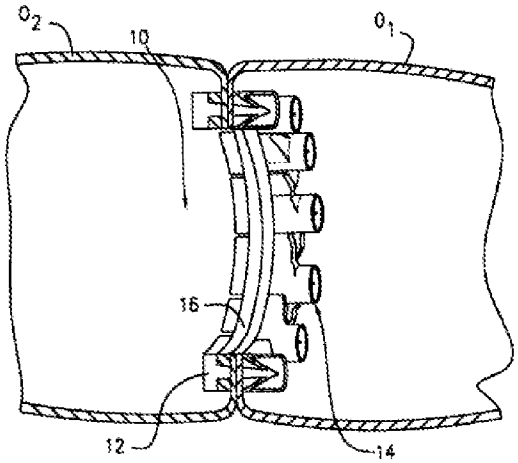

FIG. 8 of Huxel

1. The rationale for combining Hardy and Huxel fails to meet the preponderance of evidence standard with respect to the propriety of their combination

In the Office Action, it is asserted that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify the rings of Hardy to be expandable and contractible, as taught by Huxel et al., in order to maintain the connection between the rings and the tissue, as well as permit peristalsis." Page 3. The Applicants respectfully submit that this assertion of obviousness fails to meet the preponderance of evidence standard, as it is not at all clear how the devices of Hardy could be modified by the teachings of Huxel. Disparate features from Hardy and Huxel are merely cobbled together without regard to the teachings of these references. The Applicants thus respectfully submit that this proposed combination constitutes an impermissible hindsight reconstruction.

As previously discussed, Huxel acknowledges the existence of devices such as those taught in Hardy, explicitly discredits such devices and their methods of operation, and then sets forth a vastly different apparatus and method for creating an anastomosis. It is not clear from the Office Action how or why one skilled in the art would be prompted to combine the teachings of Hardy and Huxel, let alone how such a combination could result in the invention claimed in the Present Application.

The Applicants respectfully note that "[w]here the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another." M.P.E.P. § 2143.01. Here, the teachings of the references not only conflict, they explicitly teach away from each other. Yet the Office Action is devoid of any discussion of why one skilled in the art would be prompted to combine these oppositely directed teachings, or how one skilled in the art could even do so. Accordingly, the Applicants respectfully assert that the Office Action fails to set forth a *prima facie* case of obviousness with respect to Hardy and Huxel.

2. The proposed combination would change the principle of operation of each of Hardy and Huxel

As previously discussed, the devices of Hardy are designed to maintain a fixed diameter and to anastomose two tubular structures without penetrating the tubular structures. In contrast, the devices of Huxel do not define a diameter, or at least not in

the same manner as the devices of Hardy. It might be said that a series of the discrete components of Huxel arranged at the ends of two tubular structures define a diameter, and this diameter can change with a change in the diameter of the tubular structures. However, this diameter would constitute a diameter between separate discrete components, and would not be a diameter defined by any of the discrete components individually. In any event, the devices of Huxel operate only by penetrating the tubular structures that are being attached to each other.

In sum, any alteration of the teachings of Hardy to cause its devices to have a variable diameter would change the principle of operation of these devices. Any alteration of the teachings of Huxel to cause its devices to operate without penetrating the tubular structures that are being attached to each other would change the principle of operation of these devices. Accordingly, the Applicants respectfully assert that the Office Action fails to set forth a *prima facie* case of obviousness with respect to Hardy and Huxel.

Summary

In view of the foregoing, the Applicants respectfully submit that the rejection of claims 1-52 based on a combination of Hardy and Huxel is improper, as the Office Action fails to recite a proper *prima facie* case of obviousness with respect to these references. The Applicants thus respectfully request that the rejection of claims 1-52 under 35 U.S.C. § 103 be withdrawn.

New Claims 53-59

The Applicants respectfully maintain that claims 1-52 are patentable over all prior art of record in the Present Application. New claims 53-59 depend from independent claims 1, 7, 18-20, 31, 42, respectively, and thus the Applicants respectfully submit that these newly added claims are patentable for at least the reason that they depend from patentable independent claims.

Correction of Typographical Error

The Applicants note that a typographical error was made on page 24 of the Amendment and Response to Office Action dated October 29, 2007, which also appears on page 25 of the Resubmission of the Amendments to the Claims Section and the Remarks Section of the Amendment Filed October 29, 2007, which was filed on December 10, 2007. Specifically, the sentence: "As discussed above, the rings recited in the claims of the Present Application and its parent, U.S. Patent No. 6,736,825, are obviated by the discrete components disclosed in Huxel . . . " should instead read: "As discussed above, the rings recited in the claims of the Present Application and its parent, U.S. Patent No. 6,736,825, are not rendered obvious by the discrete components disclosed in Huxel . . . ."

CONCLUSION

In view of the foregoing, it is believed that all of the claims are patentable in their present form and thus a Notice of Allowance is respectfully requested. The Examiner is invited to contact the undersigned attorney should any impediment to the prompt allowance of this Application remain that is susceptible to being clarified by a telephonic interview or overcome by an examiner's amendment.

Additionally, the Applicants respectfully note that specific distinctions between the prior art and the claims of the Present Application have been identified in earlier Amendments to comply with the requirements of 37 C.F.R. § 1.111(b). The Applicants wish to emphasize, however, that it is the combination of features recited in each claim of the Present Application that renders it patentable, and not any feature or features of the claim in isolation.

DATED this 8th day of December, 2009.

Respectfully submitted,

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